(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 June 2001 (14.06.2001)

PCT

(10) International Publication Number
WO 01/41624 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number: PCT/IL00/00611

(22) International Filing Date:
28 September 2000 (28.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

PCT/IL99/00670	8 December 1999 (08.12.1999)	IL
PCT/IL99/00674	9 December 1999 (09.12.1999)	IL
PCT/IB00/00302	20 March 2000 (20.03.2000)	IB
PCT/IB00/00310	20 March 2000 (20.03.2000)	IB

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier applications:

US	PCT/IL99/00284 and (CIP)
Filed on	30 May 1999 (30.05.1999)
US	PCT/IL99/00285 (CIP)
Filed on	30 May 1999 (30.05.1999)

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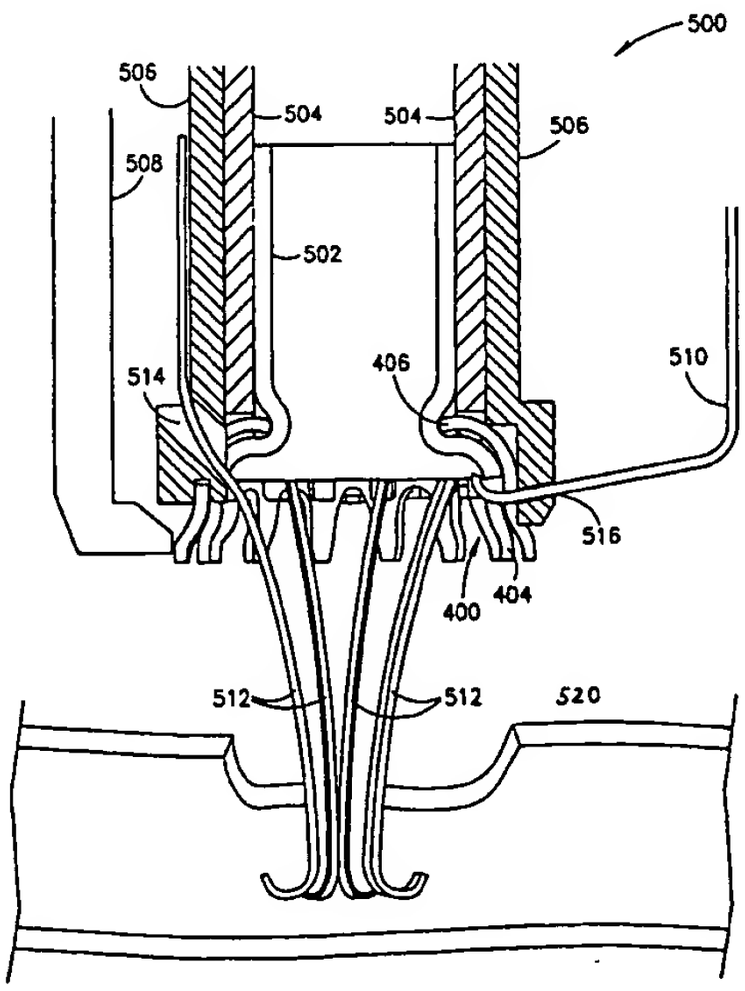
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,

[Continued on next page]

(54) Title: VESSEL LIP ATTACHMENT



(57) Abstract: A vascular attachment device for sealing an opening between two blood conduit lips, comprising: at least one clip element adapted for sealing at least a portion of an opening between two blood conduit lips; and at least one puller adapted for pulling, inside the body, at least one of said lips into said clip element.

WO 01/41624 A2

HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *Without international search report and to be republished upon receipt of that report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

VESSEL LIP ATTACHMENT

RELATED APPLICATIONS

The present application is related to the following PCT applications filed by applicants Bypass Inc., et al., PCT/IL99/00285, PCT/IL99/00284, PCT/IL99/00674, PCT/IL99/00670, PCT/IB00/00302 and PCT/IB00/00310, and an application filed on even date as the instant application, in the Israel Receiving Office of the PCT, titled "ANASTOMOTIC DEVICES AND METHODS", attorney docket 088/01579, all of which designate the US, the disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to the manipulation of vessel hole lips, especially for effecting anastomosis connections.

BACKGROUND OF THE INVENTION

Eversion of vessel lips is typically performed outside the body, for example as described in US patents 5,366,462 and 5,695,504, the disclosure of which is incorporated herein by reference. However, the lips of a hole in an aorta cannot be thus manipulated, since the aorta must remain in the body.

SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to eversion of the lips of a hole in a blood vessel, for example so that they are engaged by an anastomotic connector or a hole closure device. In an exemplary embodiment of the invention, a puller is used to retract the lips into the connector. Optionally, the puller is removable, for example being part of a device delivery system. Alternatively, the puller may remain in the connection. Alternatively, no puller is used, for example, a change in the device geometry causing the lips to be retracted. Alternatively to retraction into the device, the retraction is into the delivery system, after which the anastomotic device is applied. The delivery system, in some embodiments of the invention, guides the retraction.

The pullers may be used in various types of vascular devices, whereby the pullers bring the lips of the blood vessel into a desired location relative to another lip or a device, and optionally hold the lip in place, or move it, during an operation of the device. Where a plurality of pullers are provided, the pullers may, for example, act simultaneously or in sequence.

The anastomotic device may have, for example, one part, two parts or may comprise a plurality of independent (or attached by a thread) clamping elements.

The retracted lips may be pressed against each other to prevent blood leakage. Alternatively, they may be pressed against a part of the device.

An aspect of some embodiments of the invention relates to a method of attaching two blood vessel using multiple clips. In an exemplary embodiment of the invention, the lips of the two blood vessels are everted and the clips are closed onto the everted part, so that the clips remain outside the blood vessels and there is an intima-to-intima connection between the blood vessels. In some embodiments of the invention, the lips are everted using hooks that transfix the lips. Alternatively, the hooks do not transfix the lips.

There is thus provided in accordance with an exemplary embodiment of the invention, a vascular attachment device for sealing an opening between two blood conduit lips, comprising:

at least one clip element adapted for sealing at least a portion of an opening between two blood conduit lips; and

at least one puller adapted for pulling, inside the body, at least one of said lips into said clip element.

Optionally, said puller is attached to said device. Alternatively, said puller is not attached to said device.

In an exemplary embodiment of the invention, said puller is adapted to remain in a body after use. Alternatively, said puller is adapted to be removed from a body after use.

In an exemplary embodiment of the invention, said puller is bio-absorbable.

In an exemplary embodiment of the invention, said puller is adapted to penetrate said lip. Alternatively or additionally, said puller is adapted to transfix said lip. Alternatively, said puller is adapted to not penetrate said lip.

In an exemplary embodiment of the invention, said puller is adapted to be distorted by said clip. Optionally, said distortion assists in a removal of said puller from said seal

In an exemplary embodiment of the invention, said at least one puller comprises a single puller adapted to pull both of said lips. Alternatively, said at least one puller comprises two pullers, each adapted to pull one of said lips.

In an exemplary embodiment of the invention, said puller is attached to a thread, for retracting said puller. Optionally, said puller is distorted by said retracting, while pulling said lip into said clip.

In an exemplary embodiment of the invention, said at least one clip comprises a plurality of clips cooperating to seal said opening. Optionally, said plurality of clips are not connected to each other. Alternatively, said plurality of clips are interconnected. Optionally,

said plurality of clips are rigidly interconnected. Alternatively, said plurality of clips are flexibly interconnected.

In an exemplary embodiment of the invention, said clip does not distort to effect said seal. Alternatively, said clip distorts to effect said seal. Optionally, said clip comprises two arms the bend towards each other to effect said seal. Alternatively or additionally, said clip distorts plastically. Optionally, said device comprises a delivery system comprising a contra element and a pressure element, which two elements compress said clip between them.

In an exemplary embodiment of the invention, said clip self-distorts. Optionally, said device comprises a delivery system comprising a restraining element adapted to selectively release said clip, to self distort.

In an exemplary embodiment of the invention, said clip comprises barbs, for engaging said lips. Alternatively or additionally, said clip comprises protrusions, for engaging said lips.

In an exemplary embodiment of the invention, said clip comprises a slot, for engaging said lips.

In an exemplary embodiment of the invention, said clip is adapted to seal said lips against each other. Alternatively or additionally, said clip is adapted to seal said lips against a part of said clip.

In an exemplary embodiment of the invention, said clip compresses said lips, to effect said seal.

In an exemplary embodiment of the invention, said lips are lips of a same conduit. Alternatively, said lips are lips of two different conduits.

In an exemplary embodiment of the invention, at least one of said conduits is an in-vivo blood vessel. Alternatively or additionally, at least one of said conduits is a synthetic graft.

There is also provided in accordance with an exemplary embodiment of the invention, a method of sealing an opening between two blood conduit lips, comprising:

providing a clip;

first retracting a first lip into said clip; and

second retracting a second lip into said clip. Optionally, the method comprises closing said clip to seal said opening. Optionally, closing comprises releasing said clip to self-deform. Alternatively or additionally, closing comprises plastically deforming said clip.

In an exemplary embodiment of the invention, said first and second retracting are performed simultaneously. Alternatively, said first and second retracting are performed using a

single puller. Optionally, said puller has a single lip engaging element. Alternatively, said puller has at least two lip engaging elements.

In an exemplary embodiment of the invention, said first and second retracting are performed using at least two pullers.

In an exemplary embodiment of the invention, the method comprises retracting said puller from said seal. Alternatively, the method comprises leaving said puller in said seal.

In an exemplary embodiment of the invention, the method comprises providing a pharmaceutical at said seal. Optionally, said pharmaceutical comprises a clot prevention pharmaceutical. Alternatively, said pharmaceutical comprises a clot enhancing pharmaceutical.

In an exemplary embodiment of the invention, providing comprises providing a layer of material comprising said pharmaceutical. Optionally, said layer is provided between said lips

In an exemplary embodiment of the invention, said two lips are lips of an opening in a single conduit. Alternatively, said two lips are lips of different conduits.

In an exemplary embodiment of the invention, at least one of the conduits comprises a blood vessel.

BRIEF DESCRIPTION OF THE FIGURES

Non-limiting embodiments of the invention will be described with reference to the following description of exemplary embodiments, in conjunction with the figures. The figures are generally not shown to scale and any measurements are only meant to be exemplary and not necessarily limiting. In the figures, identical structures, elements or parts which appear in more than one figure are preferably labeled with a same or similar number in all the figures in which they appear, in which:

Figs. 1A-1D illustrate a blood vessel attachment method and apparatus, in accordance with an exemplary embodiment of the invention;

Fig. 1E is a top view of a clip suitable for the method illustrated in Figs. 1A-1D;

Figs. 2A-2B illustrate a blood vessel attachment method, in accordance with an alternative exemplary embodiment of the invention;

Fig. 2C illustrates an alternative blood vessel attachment device, in accordance with an alternative exemplary embodiment of the invention;

Fig. 2D illustrates an alternative clip, in accordance with an exemplary embodiment of the invention;

Figs. 3A-3D illustrate a hole-closure device based on a clip-puller combination, in accordance with an exemplary embodiment of the invention;

Fig. 4 illustrates a multi-clip connector, in accordance with an exemplary embodiment of the invention;

Figs. 5A-5F illustrate a method of deploying the clip of Fig. 4, in accordance with an exemplary embodiment of the invention;

Figs. 6A-6C illustrate an alternative method of deploying multiple clips in an anastomotic connection, in accordance with an exemplary embodiment of the invention; and

Figs. 7A-7C illustrate the deployment of other clip-devices for the attachment of two blood vessels, in accordance with exemplary embodiments of the invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Figs. 1A-1D illustrate a blood vessel attachment method, in accordance with an exemplary embodiment of the invention. In Fig. 1A, an end-vessel 100 and a side vessel 102 are attached together using a clip 104. Clip 104 comprises a first arm 106 having a vessel engaging means, for example a barb 108, for engaging vessel 100, and a second arm 110, having a vessel engaging means such as a barb 112 for engaging vessel 102. In this and in other embodiments, the blood vessels and/or grafts may be part of the natural vasculature, synthetic, autologus, xenologus, cadaver grafts and/or any other type of blood conduit.

In Fig. 1A the two vessels are engaged by the barbs, such that a lip 114 of vessel 100 is engaged by barb 108 and a lip 116 of vessel 102 is engaged by barb 112. The two lips may abut or there may be a space between them.

In Fig. 1B, clip 104 is folded so the intima portions of the two lips are pressed against each other by the two arms of the clip. The barbs prevent an inadvertent release of the vessel lips during the conformance change and/or provide stability after the connection is completed.

The conformance change of the clip may be effect in various ways, for example elastically, super-elastically or using a shape memory clip, in which cases no external forces may be required. Alternatively, clip 104 is plastically deformed.

Although clip 104 is shown in Fig. 1A having an angle greater than 180° between the arms holding the barbs, in some embodiments, clip 104 is flat or has an angle smaller than 180°, so that the clip can be squeezed shut using a pliers or a clamping scissors. The angle between the arms may affect the ease of mounting the lips of the vessels onto the barbs.

Figs. 1C and 1D illustrate the use of a puller for retracting the vessel lips onto the barbs. Fig. 1C shows a puller 120 including a curved tip 122 for pulling lip 114 of vessel 100 onto barb 108. Fig. 1D shows a puller 124 including a curved tip 126 for pulling lip 116 of vessel 102 onto barb 112. Alternatively, other methods of mounting may be used, for example

manual mounting. An exemplary device for carrying out the method of Figs. 1C-1D is described below.

In some embodiments of the invention, tip 126 (and 122) is sharp. Alternatively, tip 126 may be blunt, for example to prevent penetration of the tip into the blood vessel wall engaged by the tip. Tip 126 may also be forked, for example, to prevent over penetration of the tip into the blood vessel wall.

Although the above clip is shown for use on side-to-end anastomosis connections, it may also be used for other types of connections, for example, end-to-end connections and side-to-side connections.

Fig. 1E is a top view of a clip suitable for the method illustrated in Figs. 1A-1D. In this exemplary embodiment, clip 104 comprises an elliptical ring, one side of which is arm 106 and the other side of which is arm 110. The barbs are formed at the apexes of the ellipse. Two cross-bars 130 are provided to allow the clip itself to be used as a pivot for pullers 120 and 124. In an alternative embodiment, clip 140 is bar shaped. As will be described below, a complete anastomosis may require several such clips, or a multi-clip connector.

Figs. 2A-2B illustrate a blood vessel attachment method, in accordance with an alternative exemplary embodiment of the invention. A clip 204, which may be the same as clip 104 of Fig. 1, is mounted on vessel 100 and 102. A single puller 220 including two barbs 222 and 226, one for each vessel is shown instead of two separate pullers. This puller is optionally used for mounting the vessels on clip 104 of Fig. 1. A contra element 232, comprising two spaced apart portions is placed behind clip 104, opposite from barbs 222 and 226. When puller 220 is retracted towards contra element 232, clip 204 is pulled between the contra element portions and bend, thus clamping the two blood vessel lips between the arms. The resulting completed connection is shown in Fig. 2B. Contra element 232 optionally includes an extension 236 on one or both portion, to prevent over retraction of clip 204. Optionally, contra elements 232 are brought closer together, to further seal the anastomosis by bending clip 204. Contra elements 232 may be removed after the procedure is completed such that only clip 204 stays in the body.

Puller 220 may be cut at point 234, thus keeping barbs 222 and 226 inside the anastomosis connection. Possibly, the barbs are bio-absorbable. Alternatively or additionally, the barb includes a tissue bonding enhancing material. Alternatively or additionally, the barbs are pulled out of the vessels, possibly tearing the lips of the vessel, at portions outside of the connection area. In one embodiment of the invention, the barbs are shorter than the thickness of the vessel wall, so the tear is not complete. Possibly, barbs 222 and 226 soften at body

temperature or in a liquid or electrolytic environment, allowing them to be pulled out. Alternatively barbs 222 and 226 are bent back by bars 130 (Fig. 1E) allowing them to be more easily retracted. Alternatively or additionally, barbs 222 and 226 are not sharp and do not penetrate the vessel wall, but merely pull it back and then can slide past the wall, possibly deforming, and out of the connector. Alternatively or additionally, puller 220 may be connected to the rest of the clip, for example, using a thread or wire.

Fig. 2C illustrates an alternative blood vessel attachment device 240, in accordance with an alternative exemplary embodiment of the invention. Device 240 comprises a clip 242 and a puller 244, generally similar to clip 104 and clip 204. However, clip 242 is pre-bent. Thus, puller 244 is required to pull the tissue lips into a narrow space 246 formed between the two arms of clip 242. Barbs 248 can prevent retraction of the lips, once pulled into space 246. In some embodiments of the invention, space 246 includes a wall (not shown) that divides the space into two spaces, one for each lip. Alternatively or additionally to a wall, a gauze, pad or bioabsorbable material may be provided as a layer between the two lips and/or between the lisp and the device. In an exemplary embodiment of the invention, the layer elutes heparin or other blood coagulation promoters or antagonists, for example, to prevent clots or to promote clotting of leakage blood. Other pharmaceuticals may be provided as well. The pharmaceutical may be soaked in the layer, or, for example, it may be trapped in a matrix, so that it is slowly released over time.

Fig. 2D illustrates an alternative clip 252, in accordance with an exemplary embodiment of the invention. The above described clips, for example that of Fig. 1E have opposing arms. However, this is not required. Clip 252 has one arm 253 on one side of a base 256 and two arms 254 on an opposite side. A matching asymmetric puller 250 is also shown, that has two puller barbs 260 opposing a single puller barb 260, on a thread 262. Arms 253 and 254 may include barbs, as described above. However, in an exemplary embodiment of the invention, the vascular tissue is pinched between the two arms 254, possibly being forced into the space between arms 254 by arm 253. Optionally, the arms extend at an angle, so the space between the arms is more wedge shaped. Possibly, the distance between the arms is shorter than the combined width of the two target blood vessels. Alternatively or additionally, arms 254 can be elastically distorted, to accommodate a greater width of tissue.

Figs. 3A-3D illustrate a hole-closure device 300 based on a clip-puller combination, in accordance with an exemplary embodiment of the invention. Although Figs. 1 and 2 are described with reference to attaching two lips from different blood vessels, similar principles

may be applied to vascular hole closure, in which the two lips that are sealed together are from a same blood vessel.

Fig. 3A shows a hole closure device 300, in a layout view. In Fig. 3B, device 300 is folded, such that it has a base 302 and two arms 304, each arm having one or more barbs 306 at its ends.

Fig. 3C shows a device 300 being deployed. In an exemplary embodiment of the invention, device 300 is held against a vessel 312, adjacent a hole 310 therein, by a contra-tube 320, which may be hollow. Alternatively, device 300 may be mounted on tube 320. Hole 310 has lips 318 and 320, that can be pulled into device 300, by a puller 314. Possibly, puller 314 is pulled using a thread or wire 316, which optionally extends through tube 320.

Fig. 3D shows hole 310 after puller 314 pulls lips 318 and 320 into device 300. Puller 314 (which may remain in the connection) is not shown, for example being retracted (possibly through the hole in base 302, optionally after being bent back by contact with base 302 itself) or being absorbed, as described above. Device 300 may be sized to fit various hole sizes and blood vessel thickness. Alternatively or additionally, a flat device, for example as shown in Fig. 3A is bent, on the spot, to match desired hole closure characteristics. Although device 300 is shown with two barbs 306 on each arm, a greater or smaller number of barbs may be provided, possibly not opposing barbs, or even protrusions (not sharp) instead of barbs. The length of the device may depend, for example on the size of hole 310. Alternatively or additionally, a plurality of devices 300 are applied size by side.

Similarly, the clips of Figs. 1-2 may be provided as individual clips, for example, one by one or using a multi-clip delivery system, for example for simultaneous delivery. Typically, several clips are required for connecting two blood vessels together, for example, 3, 4, 5, 6 or more clips. Alternatively, the clips may be connected together, for example using a thread or a ring, to form a single anastomosis connector (or hole closure device). Alternatively, previously described connectors and hole closure devices (e.g., in the above PCT applications) may be segmented to provide clips, for example each clip comprising two opposing spikes and an optional ring section.

Alternatively or additionally to bending of the spikes/arms, a torsion bar mechanism may be provided for rotation of the arms. In an exemplary embodiment of the invention, base 256 of clip 252 in Fig. 2D can serve as a torsion bar, that twists alternatively or additionally to bending of arms 254 and 253. Clip 252 can then be a pressure based clip, which simply forcefully contacts two vascular tissues.

Fig. 4 illustrates a multi-clip connector 400, in accordance with an exemplary embodiment of the invention. Connector 400 comprises a ring 402 having a plurality of "side" engaging clips arms 404 and an opposing plurality of "end" engaging clip arms 406. As shown, opposing clips arms do not need to have a same radial position, however, that is possible. Alternatively or additionally, the number of "side" and "end" clip arms may be different. Alternatively or additionally, the connector may be used for two "side" vessel or for two "end" vessels. As shown the clip arms are not designed to penetrate the vessel walls, however, in some embodiments, at least some of the clip arms may penetrate the vessel walls, such arms may include a fork design or a protrusion distal from their tip, to prevent over penetration and/or motion of the vessel wall along the arm. The clip arms on opposing sides may have the same or a different general design. Alternatively or additionally, the clip arms on a same side of ring 402 may also be the same (as shown) or different, for example alternating clip arms having different designs.

Figs. 5A-5F illustrate a method of deploying the clip of Fig. 4, in accordance with an exemplary embodiment of the invention. In these figures, not all the repeating elements are shown, to reduce visual clutter. System 500 may be deployed, for example in open surgery, in endoscopic or throactoscopic surgery and/or in a transvascular approach.

Fig. 5A illustrates a delivery system 500 having mounted therein a graft 502 and a connector 400. The view is a cross-sectional view selected so that the operation of one "side" arm 404 and one "end" arm 406 are clearly visible.

System 500 includes an outer contra tube 506 and an inner pusher tube 504. Connector 400 is held, for example elastically or by friction, by outer contra tube 506. An outer base tube 508 is provided for closing the "side" arms, as will be described below. A plurality of "side" vessel pullers 512 are provided through apertures 514 formed in outer tube 506. A plurality of "end" vessel pullers 510 are provided through apertures 516 formed in outer tube 506. In an exemplary embodiment of the invention, arms 504 and 506 are staggered, so that apertures 514 and 516 are staggered to match the arm locations. The tips of the pullers may or may not be aligned with the arms into which they pull vascular tissue. In some embodiments, at least some of the pullers may be non-planar.

In Fig. 5B, "end" pullers 510 are retracted, pulling the lips of graft 502 against clip device 400. This step may be performed inside the body or outside of it.

Fig. 5C shows system 500 near a target side vessel 520. Target vessel 520 may be, for example, a coronary artery, a synthetic or biological graft, an aorta, a LIMA, a coronary vein, an aorta or a peripheral blood vessel, such as a femoral artery or a leg vein, or any other known

blood conduit. Also graft 502 may be any known blood conduit. Pullers 512 are extended forward so that they enter an opening in vessel 520. In some embodiments of the invention, the insertion of pullers 512 is manual. In others, it is facilitated by an alignment of system 500 and the hole in the target vessel. It is noted that a punch for forming the opening may be provided through outer base tube 508 and then replaced with the graft delivery portion. Alternatively, a punch may be provided through graft 502. Alternatively, a separate punching tool is used. Alternatively, an incision is made using a knife.

In Fig. 5D, pullers 512 are retracted, pulling the lips of the incision of vessel 520 into the clip, so that the lips of the two vessels are near, touching or overlapping each other.

In Fig. 5E, a proximal inwards pointing portion 522 of base 508 is pushed inwards, causing arms 404 to close on the lips of vessel 520, and in the process possibly also everting them further. Portions 522 may include an inclined portion 526 for guiding the arms to close in a desired fashion. One exemplary method of moving portions 522 is advancing an outside tube 524 over base outer tube 508, causing it to radially compress. Although puller 512 may be distorted during the closing of arms 404, this is generally of no consequence.

In Fig. 5F, inner pusher tube 504 is advanced, closing arms 406 of clip 404. Base tube 508 may serve as a contra for the pressure. The blood vessels are thus held securely between arms 404 and 406, preferably preventing blood leakage.

In some embodiments of the invention, the steps of Figs. 5E and 5F are performed simultaneously or in an a opposite order. Although simultaneous performance for all the arms on a side is preferred, in some embodiments, not all the arms on a single side are closed together.

The anastomosis being completed, pullers 512 and 510 may be retracted and base tube 508 can be radially expanded, to release clip 400. Inner tube 504 may be advanced further to release clip 400 from outer tube 506. Alternatively, the pullers may be dealt with as described above, for example, cut and left in the body, possibly to be absorbed.

The above, described the deployment of a plastically deployed device. In an elastic, shape-memory or super-elastic device, a similar delivery system may be used. For example, base tube 508 may include barbs or an inner lip for maintaining arms 404 open (until base tube 508 is advanced) and inner tube 504 may include an extension for preventing arms 406 from closing (until inner tube 504 is retracted). Even in a plastically deformed device 400, ring 402 may be elastic, for example to allow radial compression for deployment and/or for being held by outer tube 506.

Although Fig. 5 above and Fig. 6 below describe a side-to-end anastomosis, it should be appreciated that a similar mechanism may be used for oblique, side-to-side and end-to-end connections. In such connections, the vessel may be aligned in a non-axial manned to the rest of delivery system 500, for example, be provided through a lumen that is perpendicular to the system axis. However, the general working of the pullers remains the same.

Alternatively or additionally, system 500 is a split system (into two, three or more lengthwise parts), so that it can be more easily removed from graft 502.

Figs. 6A-6C illustrate an alternative method of deploying multiple clips in an anastomotic connection, in accordance with an exemplary embodiment of the invention.

Fig. 6A shows a graft 602, having a lip 604 transfixed on a puller 606. A delivery system 600, mounted on the graft includes an inner tube 620 on which an anastomotic connector 608 is mounted. Connector 608 may comprise, for example, a ring 616 and a plurality of clip arms 618. In an exemplary embodiment of the invention, connector 608 is super-elastic, elastic or shape memory, with arms 618 prevented from folding in by a restraint 626. In an exemplary embodiment of the invention, an inwardly pointing extension 610 of restraint 626 includes a circumferencially pointed (e.g., out of the figure plane) bump 612 (or restraint 626 is slotted) that prevents arm 618 from radial motion. When restraint 626 is rotated relative to connector 608 or when restraint 626 is radially expanded, arms 618 are released.

Delivery system 600 further comprises a retracting tube 624 for retracting pullers 606 and a contra tube 622 which prevents retraction of connector 608.

In Fig. 6B, pullers 606 are extended into an incision 634, having lips 632 in a "side" vessel 630.

In Fig. 6C, pullers 606 are retracted, everting lips 632 and pulling both lips 632 and lips 604 into connector 608. Restraint 626 then releases arms 618, allowing the connector to close, sealing the connection between graft 602 and vessel 630. Pullers 606 are thus generally not required any more, at least not for holding vessel 630. Pullers 606 can then be further retracted, possibly causing no damage to the blood vessels, as the pullers are straightened by the retraction. Connector 608 can be released, for example by advancing contra tube 622. In a plastically deformed embodiment, restraint 626 acts as a anvil, to radially compress arms 618.

Arms 618 may have sharp tips, as shown, for example to penetrate one or both of lips 632 and 604. Alternatively, the tips of arms 618 may be blunt, to apply non-penetrating pressure. Alternatively, arms 618 may hold lips 604 against the upper part of the connector and lips 632 against the ring part of the connector.

It should be noted that while Figs. 5 and 6 illustrate anastomotic connectors, a similar delivery system may be used for connecting two lips of a single blood vessel, for example for hole closure. In such a case, the connector, instead of being a ring as shown in Fig. 4, may be a line connector or a circular connector with arms only on its bottom part, pointing in.

Figs. 7A-7C illustrate the deployment of other clip-devices for the attachment of two blood vessels, in accordance with exemplary embodiments of the invention.

In Fig. 7A, a clip 700 is elastic, super-elastic of shape memory, so that it desires to reach a folded shape (i.e., is self-closing). A restraint 706, including, for example a slotted portion 712 that engages an arm 708 of clip 700, prevents the arm from closing. Another arm 710 of clip 700 may be held in another slot (or bump) 714. Alternatively, clip 700 is part of a single connector including a plurality of clips attached to a ring 716, here shown being held by a holder 718.

In operation, the lip of a graft 702 is transfixed by arm 708 of clip 700. Arm 708 is inserted into an incision in a vessel 704 (only one side shown). When restraint 706 releases clip 700, the clip closes, sealing together graft 702 and vessel 704. In a plastically deformed embodiment, a retraction of restraint 706 may fold arm 708 against arm 710.

Fig. 7B shows an alternative embodiment of the invention, in which a self-closing clip 720 transfixes a graft 702 and a vessel 704. The clip maybe inserted, for example, manually, into an incision in vessel 704 and then embedded in the vessel wall by pulling it back. When a restraining outer tube 722 is retracted, clip 720 is free to fold. Like clip 700, also clip 720 may be part of a multi-clip connector, in some embodiments of the invention.

Fig. 7C shows an alternative embodiment of the invention, in which a clip 730 has the lips of graft 702 and vessel 704 inserted into it, for example manually or using a puller (not shown). Clip 730 comprises two arms 732 and 734 connected by a base 736. In an exemplary embodiment of the invention, clip 730 is pre-stressed so that arms 732 and 734 desire to fold inwards. Arms 732 and 734 extend past base 736 as extensions 742 and 744, respectively. A restraint comprising two opposing restraint elements 738 and 740 engage and maintain in position, clip 730, via extensions 742 and 744. Clip 730 is a self-closing clip, in which arms 732 and 734 close towards each other. When restraints 738 and 740 are brought apart, arms 732 and 734 advance towards each other and engage and seal together the lips of graft 702 and vessel 704. In an exemplary embodiment of the invention, restraints 738 and 740 are brought together in order to enlarge the distance between arms 732 and 734 and make it easier to insert the lips of vessel 704 and graft 702 into the clip. Possibly, clip 730 is laid against the vessel

and the graft and as the restraints are let apart, the tips of arms 732 and 734 engage and advance the lips into the clip.

The above devices may be varied in various ways, for example for adaptation for specific types of blood conduits. In some embodiments of the invention, a device is packaged and/or sold with an instruction leaflet, describing the device dimensions and/or situations for which the device should be applied.

One or more of the following parameters of a device may be varied, for example:

(a) Number of barbs in an arm of a clip. Although only one barb is shown, two, three or more barbs may be provided.

(b) Location of barbs along the arm. Although the barbs are shown at the tip of the arm, they may be positioned further in. In devices with multiple barbs, the barbs may be positioned side by side or one in front of the other, for example.

(c) Shape of arms. Various shapes may be provided, for example, rectangular, triangular, arcuate, circular and piecewise linear or curved. The arms may be planar or may extend outside of a plane, for example being curved.

(d) Length of barbs. The barbs may be long enough to transfix the vessel walls. Alternatively, they may be made shorter, for example penetrating only some of the layers of the blood vessel. It is noted that different barbs on a same device may have different lengths or other properties, for example, depending on the properties of the target vessels. Exemplary lengths include, 0.1 mm, 0.5 mm, 1 mm, 2 mm and larger, smaller and intermediate sizes. Other parameters of the barb design may vary as well, for example the degree of sharpness (sharp vs. blunt).

(e) Length of arms. The length of the arms may also depend on the properties of the target vessels and the geometry of the connection. Exemplary lengths include, 1 mm, 3 mm, 5 mm, 7 mm and larger, smaller and intermediate sizes.

(f) Existence and dimensions of base. Although not all devices include a base, the length of the base may be, for example, 1 mm, 3 mm, 5 mm, 7 mm and larger, smaller and intermediate sizes. The width of the base (between two arms) may be, for example, 0.5 mm, 1 mm, 3 mm, 5 mm and larger, smaller and intermediate sizes.

(g) Existence and geometry of lumen. In devices with a central lumen, the shape of the lumen and the punched hole may be vary, for example being circular, elliptical or polygonal.

(f) Solidity of device. Although the device may have a continuous surface, in some embodiments of the invention, for example as shown in Figs. 3A and 1E, one or more holes may be formed in the surface of the device. This may reduce the total amount of foreign

material in the body. It is noted, however, that the total amount of material in the blood flow may be very low or even zero, in some embodiments of the invention.

It will be appreciated that the above described methods and devices of vascular manipulation may be varied in many ways, including, changing the order of steps, which steps are performed inside the body and which outside, the order of making the anastomosis connections, the order of steps inside each anastomosis, the exact materials used for the anastomotic connectors, which vessel is a "side" side and which vessel (or graft) is an "end" side of an end-to-side anastomosis and/or whether two lips that are connected are from a same vessel or from different vessels. Further, in the mechanical embodiments, the location of various elements may be switched, without exceeding the sprit of the disclosure, for example, switching the moving elements for non-moving elements where relative motion is required. In addition, a multiplicity of various features, both of methods and of devices have been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every similar exemplary embodiment of the invention. Further, combinations of the above features, from different described embodiments are also considered to be within the scope of some exemplary embodiments of the invention. In addition, some of the features of the invention described herein may be adapted for use with prior art devices, in accordance with other exemplary embodiments of the invention. The particular geometric forms used to illustrate the invention should not be considered limiting the invention in its broadest aspect to only those forms, for example, where a circular lumen is shown, in other embodiments an oval lumen may be used.

Also within the scope of the invention are surgical kits which include sets of medical devices suitable for making a single or a small number of anastomosis connections. Measurements are provided to serve only as exemplary measurements for particular cases, the exact measurements applied will vary depending on the application. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like means "including but not limited to".

It will be appreciated by a person skilled in the art that the present invention is not limited by what has thus far been described. Rather, the scope of the present invention is limited only by the following claims.

CLAIMS

1. A vascular attachment device for sealing an opening comprising:

at least one clip element adapted for sealing at least two blood conduit lips; and

at least one puller adapted for pulling, inside the body clip element.

2. A device according to claim 1, wherein said puller is a

3. A device according to claim 1, wherein said puller is r

4. A device according to claim 1, wherein said puller is use.

5. A device according to claim 1, wherein said puller i body after use.

6. A device according to claim 1, wherein said puller is b

7. A device according to claim 1, wherein said puller is a

8. A device according to claim 1, wherein said puller is a

9. A device according to claim 1, wherein said puller is a

10. A device according to claim 1, wherein said puller is clip.

11. A device according to claim 10, wherein said distor puller from said seal